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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,440	04/20/2004	Mark R. Vandlik	F-5482 DIV 2 (0360-0159.	5464

44926 7590 04/02/2007
BAXTER HEALTHCARE CORPORATION
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DEERFIELD, IL 60015

EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/828,440

Applicant(s)

VANDLIK ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/10/04, 6/10/04, 7/21/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. It is noted that this application appears to claim subject matter disclosed in prior Application Nos. 09/390,265 and 09/390,268, filed 3 September 1999. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e),

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120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

2. Applicant has attempted to claim priority to the cross-referenced applications listed above by listing them as related applications in the first paragraph of the specification. However, applicant has failed to note the relationship (i.e., divisional,

continuation, continuation-in-part) between the instant applications and the earlier filed applications. As such, the priority claim fails to comply with 37 CFR 1.78(a), and applicant has not received the priority benefit of the earlier-filed cases.

Specification

3. The disclosure is objected to because of the following informalities: Applicant's priority claim (see explanation above) is incomplete for failing to specify the relationship between the copending applications.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,628,908 to Kamen et al in view of US 6,106,727 to Krasnoff et al.

In the specification and figures, Kamen discloses the device substantially as claimed by applicant. In particular, Kamen discloses a fluid handling system that may be attached to a patient (rendering the system suitable for blood processing as recited by applicant in the preamble, see column 3, lines 10-20). The processing system comprises a fluid flow cassette comprising tubing for connection to a patient and other processing components (see column 6, lines 41-57). The cassette 24 comprises a body 58/60, pump chambers P1 and P2 contained within the body, valve stations V1 to V10, a flexible diaphragm 59, 61 overlying the body, pump chambers, and valve stations, and flow paths F1 to F9 that extend through the cassette body (see column 7, lines 36-64).

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The number and arrangement of the pump chambers, liquid paths, and valve stations may vary (see column 7, lines 63-64). The flexible diaphragm flexes in response to fluid pressure from an actuator 76 that moves fluid through the pump chambers, valve stations, and fluid paths in and out of the cassette to the patient or other system components as desired by the operator (see column 8, lines 40-65, column 9, lines 13-40). The cassette further comprises flow paths or cavities F1 and F2 that serve as air traps for air conveyed from the pump stations (see column 10, lines 13-32).

Kamen fails to disclose that the fluid processing system comprises a filter to remove leukocytes from the fluid flowing through the processing cassette. Krasnoff discloses an apparatus and method for processing blood including a fluid handling assembly 10 that may be preconnected into a contained single system, such as a cassette (see column 7, lines 35-44). Krasnoff discloses that the disclosed processing system may comprise a porous leukocyte depletion medium (corresponding to applicant's filter) in order to improve the storage life of the other separated components (see column 1, lines 38-47). Therefore, it would have been obvious to add a leukocyte filter as disclosed by Krasnoff to the fluid handling cassette and associated patient-connected tubing disclosed by Kamen in order to provide a compact, preconnected blood handling assembly that reduces leukocyte contamination to prolong the storage life of blood components, as taught by Krasnoff.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,628,908 to Kamen et al in view of US 6,106,727 to Krasnoff et al, further in view of US 4,526,515 to DeVries et al.

In the specification and figures, Kamen and Krasnoff disclose the device substantially as claimed by applicant with the exception of a filter medium within the air trap cavity within the cassette. DeVries discloses a fluid pumping apparatus that may be used to process blood in an extracorporeal circuit (see column 1, lines 20-25). The apparatus comprises tubing, valves, pumps, and an air bubble trap with filter 86 contained within cassette 11 (see FIG 4, column 4, lines 24-34). The filter assists in the removal of air from the fluid circulating within the cassette so that harmful air bubbles and debris are not transferred back to the patient (see column 6, lines 49-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add an air bubble trap/filter as disclosed by DeVries to the cassette and filter assembly disclosed by Kamen and Krasnoff in order to prevent the transfer of harmful air bubbles and debris to the patient.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

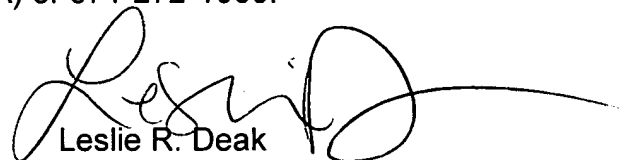
- a. US 5,954,971 Pages et al
 - i. Blood processing methods and apparatus with leukocyte filter

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Leslie R. Deak', with a long horizontal flourish extending to the right.

Leslie R. Deak
Patent Examiner
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29 March 2007